

MAR. 24. 2004 3:13PM

6508454166

NO. 8517

OFFICIAL

**RECEIVED
CENTRAL FAX CENTER**

MAR 24 2004



Incyte Corporation
Legal Department
3160 Porter Drive
Palo Alto, CA 94304
Telephone: (650) 855-0555
Facsimile: (650) 845-4166
(650) 849-8886

Date: March 24, 2004
To: Examiner Richard G. Hutson
Group Art Unit 1652
Company: USPTO
Fax No.: 703-872-9306
Telephone No.: 571-272-0930
From: Susan K. Sather, Reg No. 44,316
Our Ref. No.: PF-0635-2 DIV
Your Ref. No.: 10/025,730
Page(s): 11 , including cover sheet

Comments:

This facsimile is intended for the addressee only and may contain confidential information. If you have received this facsimile in error, please call us at 650.855.0555 immediately to arrange for its return.

Docket No.: PF-0635-2 DIV

Certificate of Transmission

I hereby certify that this paper is being facsimile transmitted to the attention of Examiner Richard G. Hutson, Group Art Unit 1652, U.S. Patent and Trademark Office to Facsimile No. 703-872-9306 on March 24, 2004.

By: [Signature]Printed: Lisa McDill

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Tang et al.Title: CALCIUM BINDING PROTEINSerial No.: 10/025,730Filing Date: December 18, 2001Examiner: Hutson, R.Group Art Unit: 1652

Attn: Examiner Richard G. Hutson
Group Art Unit 1652
Fax No.: 703-872-9306

TRANSMITTAL FEE SHEET

Sir:

Transmitted herewith are the following for the above-identified application:

1. Response to Restriction Requirement (9 pp.).

The fee has been calculated as shown below.

Claims	Claims After Amendment	-	Claims Previously Paid For	=	Present Extra	Other Than Small Entity		Additional Fee(s)	
						Rate	Fee		
Total	20	-	20	-	0	x\$18.00	0	\$	0
Indept.	2	-	3	-	0	x\$86.00	0	\$	0
First Presentation of Multiple Dependent Claims:						+290.00	0	\$	0
Total Fee:								\$	0

☒ No additional Fee is required.☐ Please charge Deposit Account No. 09-0108 in the amount of :\$ 0

The Commissioner is hereby authorized to charge any additional fees required under 37 CFR 1.16 and 1.17, or credit overpayment to Deposit Account No. 09-0108. A duplicate copy of this sheet is enclosed.

Respectfully submitted,

INCYTE CORPORATION

Date: March 24, 2004[Signature]

Susan K. Sather

Reg. No. 44,316

Direct Dial Telephone: (650) 845-4646

Customer No.: 27904
3160 Porter Drive
Palo Alto, California 94304
Phone: (650) 855-0555 or Fax: (650) 845-4166

120187

1

10/025,730

MAR. 24. 2004 3:14PM

6508454166

NO. 8517 P. 3

Docket No.: PF-0635-2 DIV

OFFICIAL

Certificate of Transmission

I hereby certify that this paper is being facsimile transmitted to the attention of Examiner Richard G. Hutson, Group Art Unit 1652, U.S. Patent and Trademark Office to Facsimile No. 703-872-9306 on March 24, 2004.

By: 

Printed: Lisa McDill

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

**RECEIVED
CENTRAL FAX CENTER**

MAR 24 2004

In re Application of: Tang et al.

Title: CALCIUM BINDING PROTEIN

Serial No.: 10/025,730

Filing Date: December 18, 2001

Examiner: Hutson, R.

Group Art Unit: 1652

Attn: Examiner Richard G. Hutson
Group Art Unit 1652
Fax No.: 703-872-9306

RESPONSE TO RESTRICTION REQUIREMENT UNDER 35 U.S.C. 121

Sir:

This paper is responsive to the Restriction Requirement and Request for Election dated February 24, 2004, setting a 1-month term for response.

Doc No.120166

1

10/025,730

Docket No.: PF-0635-2 DIV

IN THE SPECIFICATION

Please replace the paragraph immediately following the title with the following rewritten paragraph.

This application is a divisional application of U.S. application serial number 09/470,253, filed December 22, 1999, now U.S. Patent No. 6,365,371, issued April 2, 2002, which is a divisional application of U.S. application serial number 09/190,965, filed November 13, 1998, now U.S. Patent No. 6,071,721, issued June 6, 2000, both entitled CALCIUM BINDING PROTEIN, all of which applications and patents are hereby incorporated herein by reference.

IN THE CLAIMS

This listing of the claims replaces all prior versions of the claims in the application.

1. (Original) An isolated polypeptide selected from the group consisting of:
 - a) a polypeptide comprising an amino acid sequence of SEQ ID NO:1,
 - b) a polypeptide comprising a naturally occurring amino acid sequence at least 90% identical to an amino acid sequence of SEQ ID NO:1,
 - c) a biologically active fragment of a polypeptide having an amino acid sequence of SEQ ID NO:1, and
 - d) an immunogenic fragment of a polypeptide having an amino acid sequence of SEQ ID NO:1.
2. (Original) An isolated polypeptide of claim 1, having a sequence of SEQ ID NO:1.
3. (Original) An isolated polynucleotide encoding a polypeptide of claim 1.
- 4.-10. (Canceled)
11. (Original) An isolated antibody which specifically binds to a polypeptide of claim 1.
12. (Original) An isolated polynucleotide selected from the group consisting of:
 - a) a polynucleotide comprising a polynucleotide sequence of SEQ ID NO:2,
 - b) a polynucleotide comprising a naturally occurring polynucleotide sequence at least 90% identical to a polynucleotide sequence of SEQ ID NO:2,
 - c) a polynucleotide complementary to a polynucleotide of a),
 - d) a polynucleotide complementary to a polynucleotide of b), and
 - e) an RNA equivalent of a)-d).
- 13.-57. (Canceled)

Docket No.: PF-0635-2 DIV

58. (New) The antibody of claim 11, wherein the antibody is:

- a) a chimeric antibody,
- b) a single chain antibody,
- c) a Fab fragment,
- d) a F(ab')₂ fragment, or
- e) a humanized antibody.

59. (New) A composition comprising an antibody of claim 11 and an acceptable excipient.

60. (New) A method of diagnosing a condition or disease associated with the expression of HCBP in a subject, comprising administering to said subject an effective amount of the composition of claim 59.

61. (New) A composition of claim 59, wherein the antibody is labeled.

62. (New) A method of diagnosing a condition or disease associated with the expression of HCBP in a subject, comprising administering to said subject an effective amount of the composition of claim 61.

63. (New) A method of preparing a polyclonal antibody with the specificity of the antibody of claim 11, the method comprising:

- a) immunizing an animal with a polypeptide having an amino acid sequence of SEQ ID NO:1, or an immunogenic fragment thereof, under conditions to elicit an antibody response,
- b) isolating antibodies from said animal, and
- c) screening the isolated antibodies with the polypeptide, thereby identifying a polyclonal antibody which binds specifically to a polypeptide having an amino acid sequence of SEQ ID NO:1.

64. (New) An antibody produced by a method of claim 63.

Docket No.: PF-0635-2 DIV

65. (New) A composition comprising the antibody of claim 64 and a suitable carrier.

66. (New) A method of making a monoclonal antibody with the specificity of the antibody of claim 11, the method comprising:

- a) immunizing an animal with a polypeptide having an amino acid sequence of SEQ ID NO:1, or an immunogenic fragment thereof, under conditions to elicit an antibody response,
- b) isolating antibody producing cells from the animal,
- c) fusing the antibody producing cells with immortalized cells to form monoclonal antibody-producing hybridoma cells,
- d) culturing the hybridoma cells, and
- e) isolating from the culture monoclonal antibody which binds specifically to a polypeptide having an amino acid sequence of SEQ ID NO:1.

67. (New) A monoclonal antibody produced by a method of claim 66.

68. (New) A composition comprising the antibody of claim 67 and a suitable carrier.

69. (New) The antibody of claim 11, wherein the antibody is produced by screening a Fab expression library.

70. (New) The antibody of claim 11, wherein the antibody is produced by screening a recombinant immunoglobulin library.

71. (New) A method of detecting a polypeptide having an amino acid sequence of SEQ ID NO:1 in a sample, the method comprising:

- a) incubating the antibody of claim 11 with a sample under conditions to allow specific binding of the antibody and the polypeptide, and
- b) detecting specific binding, wherein specific binding indicates the presence of a polypeptide having an amino acid sequence of SEQ ID NO:1 in the sample.

Docket No.: PF-0635-2 DIV

72. (New) A method of purifying a polypeptide having an amino acid sequence of SEQ ID NO:1 from a sample, the method comprising:

- a) incubating the antibody of claim 11 with a sample under conditions to allow specific binding of the antibody and the polypeptide, and
- b) separating the antibody from the sample and obtaining the purified polypeptide having an amino acid sequence of SEQ ID NO:1.

Docket No.: PF-0635-2 DIV

REMARKS**Pending Claims**

Claims 4-10 and 13-20 are canceled. Applicants submit that these claims were included in the application as filed in the interest of providing notice to the public of certain specific subject matter intended to be claimed, and are being canceled at this time in the interest of reducing prosecution costs. Applicants expressly state that these claims are not being canceled for reasons related to patentability, and are in fact fully supported by the specification as filed. Applicants expressly reserve the right to reinstate these claims or to add other claims during prosecution of this application or a continuation or divisional application. Applicants expressly do not disclaim the subject matter of any invention disclosed herein which is not set forth in the instantly filed claim.

New Claims 58-72, whose subject matter corresponds to that of previously canceled Claims 31-45, are added in this amendment.

Therefore, Claims 1, 2, 3, 11, 12, and 58-72 are pending.

Restriction Requirement

In the Restriction Requirement, the Examiner requested Applicants to elect one of the following inventions:

Group I (Claims 1-2, 17, and 18) drawn to a human calcium binding protein;

Group II (Claims 3-7 and 9, 10, 12, and 13) drawn to polynucleotides, vectors, host cells for an expression of a human calcium binding protein;

Group III (Claims 14-16) drawn to a method of detecting a polynucleotide to a human calcium binding protein;

Group IV (Claim 11) drawn to human calcium binding protein antibody;

Group V (Claim 19) drawn to a method for treating or preventing a disorder associated with decreased expression or activity of the human calcium binding protein;

Group VI (Claim 20) drawn to a method for screening a compound as an agonist of a polypeptide of claim 1; and

Group VII (Claim 8) drawn to a transgenic organism.

Docket No.: PF-0635-2 DIV

Applicants hereby elect, with traverse, to prosecute Group IV, which includes original Claim 11 and is drawn to antibodies. Applicants further submit that new Claims 58, 59, 61, 64, 65, 67, 68, 69, and 70 would also be included in Group IV and hereby also elect new Claims 58, 59, 61, 64, 65, 67, 68, 69, and 70. Applicants reserve the right to prosecute the subject matter of non-elected claims in subsequent divisional applications.

Applicants also submit that new Claims 60, 62, 63, 66, 71, and 72 are drawn to methods of making and using the antibodies of Group IV, and should be examined together with the claims of Group IV. These method claims recite a product (i.e., an antibody), which is of the same scope as the claimed antibodies being searched by the Examiner. Therefore, it would not be an undue burden on the Examiner to examine new Claims 60, 62, 63, 66, 71, and 72 since the searches for the claimed antibodies and these new method claims would substantially overlap.

Additionally, the new method claims (new Claims 60, 62, 63, 66, 71, and 72) are entitled to rejoinder upon allowance of a product claim per the Commissioner's Notice in the Official Gazette of March 26, 1996, entitled "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)" which sets forth the rules, upon allowance of a product claim, for rejoinder of process claims covering the same scope of products. See also M.P.E.P. 821.04 as follows.

Where product and process claims drawn to independent and distinct inventions are presented in the same application, applicant may be called upon under 35 U.S.C. 121 to elect claims to either the product or process. . . . The claims to the nonelected invention will be withdrawn from further consideration under 37 C.F.R. 1.142. . . . However, if applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims which depend from or otherwise include all the limitations of the allowable product claim will be rejoined.

Thus, Applicants request reconsideration and withdrawal of the Restriction Requirement and examination of Claims 11 and 58-72.

Docket No.: PF-0635-2 DIV

CONCLUSION

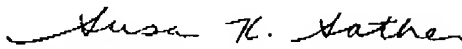
In light of the above remarks, Applicants submit that the present application is fully in condition for allowance. Early notice to that effect is earnestly solicited.

If the Examiner contemplates other action, or if a telephone conference would expedite allowance of the claims, Applicants invite the Examiner to contact the undersigned.

Applicants believe that no fee is due with this communication. However, if the USPTO determines that a fee is due or that an excess fee has been paid, the Patent Office is authorized to debit or credit (respectively) Deposit Account No. 09-0108.

Respectfully submitted,
INCYTE CORPORATION

Date: March 24, 2004



Susan K. Sather
Reg. No. 44,316
Direct Dial Telephone: (650) 845-4646

Customer No.: 27904
3160 Porter Drive
Palo Alto, California 94304
Phone: (650) 855-0555
Fax: (650) 849-8886